DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Mr. Uraiwan P. Labadini
QA & RA Manager
Belmont Instrument Corporation
780 Boston Road
Billerica, Massachusetts 01821

JAN 1 0 2017

Re: K031478
Trade/Device Name: Microheater
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: BSB, LGZ
Dated: May 9, 2003
Received: May 12, 2003

Dear Mr. Labadini:

This letter corrects our substantially equivalent letter of July 2, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809]), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) number: K031478

Device Name: Microheater

Indications For Use:

The Microheater intended use is for warming blood, blood products and intravenous solution prior to administration. It is intended to be used by healthcare professionals in clinical environments to prevent hypothermia. The system is not meant for the infusion of drugs, or platelet or granulocyte suspensions.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031478

JUL 2 2003

K031478

Attachment III

Belmont Instrument Corporation

Creating a New Standard of Care

Registered in Accordance with ISO-9001 and EN 46001

Premarket Notification
510(k) Summary of Safety and Effectiveness
[As Required By 21 CFR 807.92(a)]

1. *Submitter & Manufacturing Site:* Belmont Instrument Corporation
780 Boston Road
Billerica, MA 01821

Establishment Registration Number: 1219702

2. *Contact Person:* Uraiwan P. Labadini, Quality Assurance/Regulatory Affairs Manager

Telephone: (978) 663-0212 Ext. 28 Fax: (978) 663-0214

3. *Trade Name:* Belmont Microheater

4. *Common name:* Nonelectromagnetic Blood or Fluid Warming Device

5. *Classification name:* Blood/Fluid Warmer

6. *Product Code:* 81BSB
Device Class: Classified as a Class II device per Federal Register July, 1978.

7. *Legally marketed predicate device to which substantial equivalence is claimed:* Estill Medical Technologies, Inc. Thermal Angel™ Blood/Fluid Warmer.

8. *Brief Description:* The Belmont Microheater is a portable in-line blood and fluid warmer. It consists of three components, a heater unit, a power module which powers the heater unit and displays alarm and status messages, and a single-use disposable heat exchanger set. The heating technology used is resistive heating of two plates within the heater unit.

The Microheater warms intra-venous fluids, including blood and blood products, to physiological temperature, and monitors fluid temperature. It also senses lack of IV fluid flow, or empty cartridge, and a number of internal fault conditions including over-heating, loss of electrical connection to the heater, and failure to heat. The device stops heating and alarms if an alarm or fault condition occurs. The system provides the user with alarm, alarm message, temperature, and other operating information via a bright alphanumeric display.

The sterile disposable set is placed in-line between a standard IV line at its input and a user-supplied cannula or IV infusion set at its output. The input can come from a gravity fed IV line with roller clamp and drip chamber, external to the device and not supplied by Belmont Instrument Corp. The Microheater is not meant to be used with pressurized infusers.

The device is intended for low flow applications where the flow rate is 6 liter/hour (100 ml/min) or less.

9. *Intended Use:* The Microheater intended use is for warming blood, blood products and intravenous solution prior to administration. It is intended to be used by healthcare professionals in clinical environments to prevent hypothermia. The system is not meant for the infusion of drugs, or platelet or granulocyte suspensions.

10. *Summary of the technological characteristics of the Belmont Microheater:*

The heater unit is powered with 15 V pulsed DC which is derived from 120 or 230 VAC, 47 - 63 Hz AC/DC Converter. The temperature of the infused fluids, visual and audible alarms, and other performance characteristics of the heater unit are controlled electronically. The disposable set consists of a molded frame to which a plastic film is bonded to one side and a microporous membrane is bonded to the other to form the fluid path. The disposable set has a sterile, non-pyrogenic fluid path, and is for single-patient use only.

11. *Summary of Nonclinical Tests and Results*

In order to verify performance of the Belmont Microheater in support of substantial equivalence, the following tests were carried out:

a. Verify the ability of the system to warm cold fluids to physiological temperature.

b. Verify the ability of the system to detect and alarm at unsafe or ineffective operating conditions.

c. Verify that the device is in compliance with the following standards:

- ANSI/AAMI/ISO 11135-1994, Medical Devices, Validation and Routine Control of Ethylene Oxide Sterilization; SAL 10^{-6}.
- ANSI/AAMI/ISO 10993-1: 1995 Biological Evaluation of Medical devices - Part 1: Guidance on selection of tests.
- UL 2601-1, Underwriter Laboratories, Medical Electrical Equipment, Part 1, General requirements for Safety.
- CAN/CSA C22.2 No. 601-1-M90, Medical Electrical Equipment, Part 1, General requirements for Safety.
- EN 60601-1, Medical Electrical Equipment, Part 1, General requirements for Safety.
- EN 60601-1-2 Medical Electrical Equipment, Part 1, General requirements for Safety 2. Collateral Standard: Electromagnetic compatibility.

12. Conclusion: The Belmont Microheater Blood/Fluid Warmer is substantially equivalent to the Estill Medical Technologies, Inc. Thermal Angel™ Blood/Fluid Warmer which received 510(k) approval on July 1, 1999. Both systems have the same intended use, and are capable of heating blood products or intravenous fluids prior to administration to physiological temperature. Both systems have an independent fail-safe circuit which stops heating and alarms if the system overheats the fluid.